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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,709	10/04/2001	Qifeng Xue	50225-8073.US00	5086

7590 11/26/2003

ACLARA BioSciences Inc
1288 Pear Avenue
Mountain View, CA 94043

EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/972,709	XUE ET AL.	
	Examiner	Art Unit	
	Kaj Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It is unsigned.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4-6, 8, 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al (USP 6,375,817 B1).
4. Taylor discloses a method for separating charged sample components in a liquid sample comprising introducing a liquid sample containing charged components into a first reservoir of a microfluidic device having a first microchannel extending between, and in fluid communication with, the first and a second reservoir, and a second channel extending between, and in fluid communication with, a third and a fourth reservoir (fig. 1 and col. 6, lines 59-65), with said two channels intersecting at a junction 11 (fig. 1). Taylor further discloses applying a vacuum to a second reservoir to move sample from the first reservoir through the junction (col. 6, lines 60-

65). Because the vacuum is only applied to the second reservoir, that would inherently create a pressure differential between the second reservoir and each of the first, third and fourth reservoirs, because each of the first, third, and forth reservoirs would be at some higher unspecified pressure (presumably atmospheric pressure). After the sample is present in the junction, Taylor further discloses applying a potential difference between the third and fourth reservoirs, to produce electrophoretic separation of charged sample components present in the sample junction, as the charged components migrate from the junction toward the fourth reservoir in said second channel (fig. 2E and col. 7, lines 18-27).

5. With respect to detecting the separated sample components, see col. 14, lines 50-58.
6. With respect to the microfluidic system (those limitations not covered above), the microfluidic device of Taylor is generally planar (fig. 4).
7. With respect to the claims channel widths and depths, see col. 8, lines 36-47.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor '817.

11. With respect to claim 2, Taylor set forth all the limitations of the claim, but did not explicitly recite the use of sample comprising both positively and negatively charged species. However, one possessing ordinary skill in the art would appreciate that electrophoresis is capable of analyzing charged species irrespective of whether the species are negatively or positively charged (or both). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the method of Taylor for a sample comprising both positively and negatively charged species in order to extend the utility of the technique to all samples useable with electrophoresis.

12. With respect to claim 12, Taylor set forth all the limitations of the claim, but did not explicitly recite the set forth channel lengths. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize lengths of 3 mm to 50 cm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

13. Claims 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Dubrow et al (USP 5,976,336).

14. Taylor set forth all the limitations of the method of claim 3 or the system of claim 7, but did not disclose either the step of applying the set forth potential or the structure for applying such a potential. Dubrow teaches that adding a step of "pull back" to the injection sequence prevents bleeding of the sample from the sample channel into the separation (i.e. main) channel thereby providing a more "pinched" sample (col. 13, lines 25-40). This process of pull back reads on the potentials of claim 3 (see step 4 of the table of col. 13). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Dubrow for the method or system of Taylor in order to pinch the sample thereby providing more defined electrophoretic bands.

15. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Manz et al (USP 6,423,198 B1).

16. Taylor set forth all the limitations of the claim, but did not explicitly recite the set forth offset of the first channel. Manz teaches in an alternate microfluidic injector that a first channel may or may not be offset depending on the analysis requirements (col. 4, lines 25-52). In particular, the offset allows more sample to be injected into the separation channel (col. 6, lines 53-63). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Manz for the system of Taylor in order to allow more sample to be injected into the separation channel.

17. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Chow et al (US 2002/0046948 A1).

18. Taylor sets forth all the limitations of the claim, but does not explicitly recite the presence of detectors on opposite sides of the junction. Chow discloses in an alternate device the presence

of detectors both upstream and downstream of a juncture element in order to monitor all the potentially useful signals (paragraph 0098). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Chow for the system of Taylor in order to provide a greater understanding of the sample within the separation channel.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rossier is relevant to the claimed subject matter, but does not qualify as prior art under 35 U.S.C. 102.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a long, sweeping horizontal line extending to the right.

Kaj K. Olsen
Patent Examiner
AU 1753
November 20, 2003